510(k) SUMMARY
Bionicare® Stimulator System, Model BIO-1000™
September 14, 1998

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA) and 21 C.F.R § 807.92 . The information provided in the 510(k), premarket notification was in accordance with 21 C.F.R § 807.87 and the SMDA.

1.0 Submitter of 510(k) and Manufacturer

Murray Electronics
260 Schilling Circle
Hunt Valley, MD 21031

Attention: Kent C. Hoffman
Telephone: 410 771-0380 extension 231
Facsimile: 410 771-5576

2.0 Name of Device

2.1 Trade/Proprietary Name

Bionicare® Stimulator System, Model BIO-1000™

2.2 Common/Usual Name

TENS (Transcutaneous Electrical Nerve Stimulator)

2.3 Classification Name

Transcutaneous electrical nerve stimulator for pain relief (21CFR§ 882.5890, class II).

3.0 Identification of Predicate Device

Bionicare® Stimulator System, Model BIO-1000™
Murray Electronics
510(k) Number K971437, July 22, 1997

4.0 Device Description

The Bionicare® Stimulator System, Model BIO-1000™ is a rechargeable battery operated TENS stimulator that utilizes a voltage regulated output circuit to generate a spike-shaped pulse with an adjustable amplitude of 0-12 volts peak and repeating at a single fixed

frequency of 100 ± 5 Hertz. Electrodes are applied to the hand and arm using a standard electrode gel, Spectra 360 (Parker Laboratories NDC 341- 0012- 08). The signal is applied across the cathodic hand electrode and the anodic arm electrode.

5.0 Indications for Use

The Bionicare® Stimulator System Model BIO-1000™ is indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the hand.

6.0 Substantial Equivalence

The Bionicare® Stimulator System, Model BIO-1000™ for rheumatoid arthritis of the hand is substantially equivalent to a legally marketed predicate TENS device. The indications for use and technological characteristics of the Bionicare® Stimulator System, Model BIO-1000™ for rheumatoid arthritis of the hand and the Bionicare® Stimulator System, Model BIO-1000™ for osteoarthritis of the knee, a legally marketed predicate device, are substantially equivalent. The technical characteristics of these devices are described in Table 6.0.1.

Table 6.0.1
Device Comparison Table: Bionicare vs. Predicate Device

	Applicant Device	Predicate Device
Manufacturer	Murray Electronics	Murray Electronics
Device	Bionicare Stimulator	Bionicare Stimulator
Model No.	BIO-1000	BIO-1000
	Rheumatoid Arthritis (Hand)	Osteoarthritis (Knee)
Output Voltage	0-12 volts	0-12 volts
Frequency	100 Hertz	100 Hertz
Pulse Width	.64 ms [1]	.64 ms [1]
Waveform	monophasic spike-pulse	monophasic spike-pulse
Pulse Charge		
Max	20 µC	20 µC
ANSI NS4[2]	Meets Std.	Meets Std.
Channels	single	single
Battery Power	12 v rechargeable	12 v rechargeable
Dimensions	13.2 x 8.5 x 4.5 cm	13.2 x 8.5 x 4.5 cm
Weight (Less Battery)	235 grams	235 grams
Charger	yes	yes

[1] Pulse width fixed, measured at 50% pulse amplitude

[2] The maximum charge per pulse meets the safety and effectiveness requirements of ANSI/AAMI NS4-1985, Items 3.1-3.1.2.1, 3.2-3.2.5, 4.1-4.2.3.2

Performance Data

The descriptive characteristics presented are precise enough to ensure the substantial equivalence of the Bionicare to a legally marketed predicate device. The descriptive characteristics include the data provided in the device comparison table above, as well as, the findings of performance testing. In particular, the performance data provides greater detail regarding the Bionicare's electrical characteristics, its conformance with voluntary standards, American National Standards Institute Standard for Transcutaneous Electrical Nerve Stimulators ANSI/AAMI NS4-1985, items 3.1-3.1.3, 3.2 - 3.2.5, 4.0 - 4.2.5., Underwriters Laboratories Standard for Medical and Dental Equipment, UL 544 - July 8, 1994, Performance Section 42-Leakage Current, FDA Guide for TENS 510(k) Content, Draft August 1994, Munzner/Hinckley.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 1999

Mr. Kent C. Hoffman
General Manager
Murray Electronics
260 Schilling Circle
Hunt Valley, Maryland 21031

Re: K983228
Trade Name: Bionicare® Stimulator System, Model BIO-1000™
Regulatory Class: II
Product Code: 84 GZJ
Dated: December 15, 1998
Received: December 15, 1998

Dear Mr. Hoffman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: This response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659 Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

Device Name

Bionicare® Stimulator System, Model BIO-1000™

Indications For Use

The Bionicare® Stimulator System Model BIO-1000™ is indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the hand.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980322